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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte CHARLES S. SCHASTEEN, JACKIE GREEN, FAROOQ URAIZEE, LANCE BULL, MARY ANN PFANNENSTIEL, and TONY ALLINGTON

Appeal 2009-000311
Application 10/005,510
Technology Center 1600

Decided: September 30, 2009

Before DONALD E. ADAMS, DEMETRA J. MILLS, and ERIC GRIMES, *Administrative Patent Judges*.

MILLS, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134. The Examiner has rejected the claims for anticipation and obviousness. We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF CASE

The following claims are representative.

1. A composition for the prevention or control of coccidiosis comprising viable sporulated oocysts that are derived from an oocysts source comprising bacterial contamination and comprise at least one species of protozoa known to cause coccidiosis, wherein said composition is sterile and contains at least about 10,000 oocysts per milliliter and less than about 0.4% by weight of alkali metal dichromate, said composition being substantially free of bacterial contaminants which are present in said source but have been separated from said oocysts by tangential flow filtration of an aqueous process medium containing said oocysts and said bacterial contaminants using a filter membrane having a pore size such that sporulated oocysts cannot enter the pores, but said bacterial contaminants can pass through the pores.

30. A composition as set forth in claim 29, further comprising a composition that ameliorates a decline in a post challenge performance.

113. A kit for the prevention or control of coccidiosis comprising, the composition of claim 1; and instructions for administration of said composition to an animal.

139. A composition as set forth in claim 137 wherein said composition comprises viable sporulated oocysts of *Eimeria acervulina, Eimeria maxima,* and *Eimeria tenella* in a ratio defined by the minimum immunizing dose and amount determined by storage half life determinations.

Cited References

Brown et al.	US 6,019,985	Feb. 1, 2000
Evans et al.	WO 96/40234	Dec. 19, 1996
Conkle et al.	WO 00/50072	Aug. 31, 2000

Grounds of Rejection

1. Claims 1, 4-22, 29-30, 113-116, 118-119, 136-142, 146, 148-150, and 153-154 stand rejected under 35 U.S.C. § 102(a) as being anticipated by Conkle.
2. Claims 1, 4-30, 113-116, 118-119, 136-143, 146, 148-150, and 153-154 stand rejected under 35 U.S.C. § 103(a) over Conkle in view of Brown.
3. Claims 1, 4-22, 29-30, 113-116, 118-119, 136-142, 146, 148-150, and 153-154 stand rejected under 35 U.S.C. § 102(a) as being anticipated by Evans.
4. Claims 1, 4-30, 113-116, 118-119, 136-143, 146, 148-150, and 153-154 stand rejected under 35 U.S.C. § 103(a) over Evans in view of Brown.

FINDINGS OF FACT

Findings of Fact relevant to the rejections are set forth below.

1. Conkle teaches protozoa for use in a coccidiosis vaccine composition having an oocyst concentration of about 10^4 to about 10^6 oocysts/ml (page 3). (Ans. 3.)

2. "Conkle et al teach that in a preferred embodiment of the invention the oxidant is a biocide, hydrogen peroxide or chlorine (page 8)." *Id.* Conkle teaches the use of a bleaching agent such as sodium hypocholorite to inactivate residual microorganisms and eliminate organic matter (pages 3-4). In Conkle, a first step of separation of encysted protozoa by salt flotation or gas flotation results in about 70% encysted protozoa recovery and at least

about 80% solids. (Conkle, 5.) This dilution is centrifuged for a second time to provide a solid debris rejection rate of 90 to 99%. (Conkle, 6.)

3. Conkle teaches "compositions for the production of vaccines comprising coccidial oocysts from *Eimeria maxima, E. acevulina and E. tenella* (page 3)." *Id.* at 3.

4. The Specification discloses that "[p]ost-challenge performance improvement compositions may also be added to the sterilized sporulated oocyst suspension. A preferred post-challenge performance improvement composition is *Propionibacterium acnes* (*P. acnes*)." The Specification discloses that *P. acnes* ameliorates a decrease in post challenge performance in conjunction with a vaccine for the control of coccidiosis. (Spec. 42; original claim 25.)

5. "Conkle et al do not teach the use of *Propionibacterium acnes*." *Id.* at 8.

6. Brown teaches a method of improved immunization against coccidiosis including administering *P. acnes* as an immune stimulant and then administering a coccidiosis vaccine. (Abstract; col. 2, l. 2.) "Brown et al teach compositions comprising *Propionibacterium acnes* and normal saline used for stimulating non-specific cell mediated immune responses in poultry at an age as early as one [day] or even *in ovo* and to combat coccidiosis and other poultry diseases (column 3, lines 20-26 and column 4, lines 15-21)." (Ans. 8.)

9. The Examiner concludes that

> It would be *prima facie* obvious at the time the invention was made to add the composition comprising *Propionibacterium acnes* as taught by Brown et al to the compositions comprising oocysts from the genus Eimeria of Conkle et al because Brown et al teach compositions comprising *Propionibacterium acnes* and normal saline used

> for stimulating non-specific cell mediated immune responses in poultry at an age as early as one or even *in ovo* and to combat coccidiosis and other poultry diseases. It would be expected barring evidence to the contrary that a composition comprising sporulated oocysts, a diluent, a buffer and a bactericide would be effective in preventing coccidiosis in animals.

Id. at 9-10.

10. "Evans et al teach compositions comprising sporulated oocysts derived [from] . . . an oocysts source comprising bacterial contamination (pages 5-6)." *Id.* at 10.

11. "Evans et al teach that a typical dose of sporulated oocysts is 200,000 oocysts/bird (page 5)." *Id.*

12. "Evans et al teach that oocysts of the invention can be treated with sodium hypochlorite and then sporulated (page 5)." *Id.*

13. "Evans et al teach that potassium dichromate is removed from the suspension by repeated washing of the oocysts (page 6), therefore the claim limitation, '... less than about 0.4% by weight of alkali metal dichromate' is taught by the prior art." (Ans. 10.)

14. The Examiner finds that

> Although Evans et al teach that the oocysts of the invention can be prepared by any of several methods known to the skilled artisan (page 5), claim limitations such as ... "said composition being substantially free of bacterial contaminants which are present in said source but have been separated from said oocysts by tangential flow filtration of an aqueous process medium containing said oocysts and said bacterial contaminants using a filter membrane having a pore size such that sporulated oocysts cannot enter the pores, but said bacterial contaminants can pass through the pores are being viewed as process limitations.

Id. at 10-11.

15. The Examiner finds that the "purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art." *Id.* at 11.

16. The Examiner finds that

> In the instant case, the claims are drawn to a composition comprising oocysts and instructions for administration of the said composition to an animal. The intended use which is recited on the package insert lacks a function relationship to the composition because the insert does not physically or chemically affect the chemical nature of the composition and furthermore, the composition can still be used by the skilled artisan for other purposes. Therefore, instructions for administering the composition is unpatentable over the prior art because the composition functions equally effectively with or without the package insert, and accordingly no functional relationship exists between the instructions for use and the composition.

(Ans. 13.)

17. "Evans et al do not teach the use of *Propionibacterium acnes*." *Id.* at 14.

18. The Examiner concludes that

> It would be *prima facie* obvious at the time the invention was made to add the composition comprising *Propionibacterium acnes* as taught by Brown et al to the coccidiosis vaccines comprising oocysts of Evans et al because Brown et al teach compositions comprising *Propionibacterium acnes* and normal saline used for stimulating non-specific cell mediated immune responses in poultry at an age as early as one or even *in ovo* and to combat coccidiosis and other poultry diseases and Evans et al teach that vaccine compositions comprising *Eimeria* oocysts are effective at vaccinating poultry against coccidiosis (see the Abstract).

Id. at 15-16.

19. The Examiner finds that "It would be expected … that a composition comprising sporulated oocysts and *Propionibacterium acnes* would be effective in preventing coccidiosis in animals." *Id.* at 16.

20. Evans discloses that immune stimulants such as cytokines may be used in conjunction with its vaccine. (Evans 8, ll. 19-20.)

21. According to Appellants' Specification, the composition that ameliorates a decline or decrease in post-challenge performance includes cytokines. (Spec. 44.)

22. Evans teaches a coccidiosis vaccine with two or more species selected from *E. tenella, E. acevelina, E. maxima, E. necatrix, E. mitis, E. praecox, and E. brunetti* having at least 10 to 10^6 of each species. (Evans 3, l. 30-4, l. 2.)

PRINCIPLES OF LAW

Principles of law relevant to the rejections are set forth below.

"To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently." *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997). Thus, "[n]ewly discovered results of known processes directed to the same purpose are not patentable because such results are inherent." *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1376 (Fed. Cir. 2001).

"[A] claimed product shown to be present in the prior art cannot be rendered patentable solely by the addition of source or process limitations." *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1354 n.20 (Fed. Cir. 2003).

"The patentability of a product does not depend on its method of production. If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985) (citation omitted).

"[The] patentability of a claim to a *product* does not rest merely on a difference in the method by which that product is made. Rather, it is the product itself which must be new and unobvious." *In re Pilkington*, 411 F.2d 1345, 1348 (CCPA 1969) (emphasis added).

"Where a product-by-process claim is rejected over a prior art product that appears to be identical, although produced by a different process, the burden is upon the applicants to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product." *In re Marosi*, 710 F.2d 799, 803 (Fed. Cir. 1983).

After a *prima facie* case is made out, the burden shifts to the applicant to show a difference between the prior art compounds and the claimed compound. The PTO lacks the resources to do comparisons. *In re Best*, 562 F.2d 1252, 1255 (CCPA 1977).

> [W]here the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on.

Id. at 1254-55. *See also, In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990) ("[W]hen the PTO shows sound basis for believing that the products of the

applicant and the prior art are the same, the applicant has the burden of showing that they are not.").

"[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. . . . Whether the rejection is based on 'inherency' under 35 U.S.C. § 102, on 'prima facie obviousness' under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same . . .[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. *In re Fitzgerald*, 619 F.2d 67, 70 (CCPA 1980) (quoting *In re Best*, 562 F.2d 1252, 1255 (CCPA 1977)).

Where the only difference between a prior art product and a claimed product is printed matter that is not functionally related to the product, the content of the printed matter will not distinguish the claimed product from the prior art. *In re Ngai*, 367 F.3d 1336, 1339 (Fed. Cir. 2004). "Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention." *In re Baxter-Travenol Labs.*, 952 F.2d 388, 392 (Fed. Cir. 1991).

Arguments not made are waived. *See* 37 C.F.R. § 41.37(c)(1)(vii) ("Any arguments or authorities not included in the brief or a reply brief ... will be refused consideration by the Board, unless good cause is shown.").

1. Anticipation in view of Conkle

ISSUE

The Examiner finds that Conkle teaches the composition claimed and argues that the purification or production of a product by a particular process

does not impart novelty or unobviousness to a product when the same product is taught by the prior art.

Appellants contend that Conkle, et al. fails to disclose or suggest an oocyst-containing composition that is substantially free of bacterial contaminants that are:

> [P]resent in said source but have been separated from said oocysts by tangential flow filtration of an aqueous process medium containing said oocysts and said bacterial contaminants using a filter membrane having a pore size such that sporulated oocysts cannot enter the pores, but said bacterial contaminants can pass through the pores.

(App. Br. 11.) Thus Appellants argue that the claimed composition filters out bacterial contaminants including dead bacteria and cellular debris. (App. Br. 12.)

The issue is: Have Appellants demonstrated that the Examiner erred in finding that Conkle discloses an oocyst-containing composition that is substantially free of bacterial contaminants, particularly a composition wherein the bacterial contaminants are "present in said source but have been separated from said oocysts by tangential flow filtration of an aqueous process medium containing said oocysts and said bacterial contaminants using a filter membrane having a pore size such that sporulated oocysts cannot enter the pores, but said bacterial contaminants can pass through the pores," in other words a composition which filters out bacterial contaminants including dead bacteria and cellular debris as claimed.

ANALYSIS

Claims separately argued are addressed under separate headings herein.

Appellants urge that Conkle describes a method for preparing a vaccine against avian coccidiosis but fails to disclose or suggest an oocyst-containing composition that is substantially free of bacterial contaminants. (App. Br. 7.) Appellants urge that the composition of claim 1 "is not only substantially free of live bacteria that can be killed by sodium dichromate but is also substantially free of dead bacteria and cellular debris that are derived from the source and remain in a vaccine composition after chemical treatment." (App. Br. 7.)

We are not persuaded. "Conkle et al teach that in a preferred embodiment of the invention the oxidant is a biocide, hydrogen peroxide or chlorine (page 8)." (FF 2.) Conkle teaches the use of a bleaching agent such as sodium hypocholorite to inactivate residual microorganisms and eliminate organic matter (FF 2). A treatment that eliminates organic matter would reasonably be expected to eliminate dead bacteria and cellular debris. In Conkle, a first step of separation of encysted protozoa by salt flotation or gas flotation results in about 70% encysted protozoa recovery and at least about 80% solids. (Conkle, 5.) This dilution is centrifuged for a second time to provide a solid debris rejection rate of 90 to 99%. (Conkle, 6.) The Examiner has shown a sound basis for believing that the product of Appellants and the prior art are the same. The Appellants have the burden of showing that they are not.

The Specification, Example 4, page 53 indicates that an intermediate tangential flow filtration step results in less than about 7.5% solids in

suspension, but further indicates that additional filtration is conducted. (Spec. 53, l. 20.) The Specification fails to indicate the degree of remaining solids and bacterial contaminants after further filtration.

Appellants argue that the claimed product and that of Conkle are structurally different due to the tangential filtration step resulting in a final product which is free of bacterial contaminants. (App. Br. 15-16.) However, Conkle describes a product treated to remove bacterial contamination and a product free of solid debris up to 99%. Appellants have failed to provide evidence that Appellants' claimed product differs from the product disclosed by Conkle.

Appellants urge that the washing and filtration steps of Conkle do not render a vaccine that is substantially free of bacterial contaminants. (App. Br. 12.) Appellants urge that Conkle fails to teach or disclose a filter size small enough to prevent sporulated oocysts from entering the pores but large enough to allow bacteria to pass through the pores. *Id.* Appellants urge that the filter used in tangential flow is large enough to allow bacteria to pass. Appellants urge that the composition of Conkle would comprise a greater amount of bacterial debris than the composition of claim 1. *Id.* at 13.

Appellants also argue that the claim limitation "substantially free" of a specified class of bacterial contaminants, i.e., bacterial contaminants is the limitation that makes the invention differ from that of the prior art. *Id.* at 10. Appellants urge that the claimed product is structurally different from the product of the prior art because of structural differences. *Id.* at 11. Appellants urge that Conkle et al does not teach a composition that is "substantially free" of bacterial contaminants including both viable and nonviable. *Id.* at 14.

In response to these additional arguments, for the reasons discussed herein, we do not find that Appellants have provided evidence that the claimed product is different from the one disclosed by Conkle.

The rejection of claim 1 is affirmed.

Claims 4-8, 14-22, 29-30, 113-116, 118-119, 136-142, 146, 148-150, and 153-154

Appellants argue that claims 4-8, 14-22, 29-30, 113-116, 118-119, 136-142, 146, 148-150, and 153-154 depend either directly or indirectly from claim 1 and are thus patentable for the same reasons as set forth above for claim 1 as well as for the additional elements they require. (App. Br. 21.) Appellants have not indicated specific error in the Examiner's rejection or provided specific rebuttal argument for claims 4-8, 14-22, 29-30, 113-116, 118-119, 136-142, 146, 148-150, and 153-154.

For the reasons given for claim 1 herein we also affirm the rejection of claims 4-8, 14-22, 29-30, 113-116, 118-119, 136-142, 146, 148-150, and 153-154.

Claims 9-13

Appellants argue that claims 9-13 depend either directly or indirectly from claim 1 and are thus patentable for the same reasons as set forth above for claim 1 as well as for the additional elements they require. (App. Br. 21.)

For the reasons given for claim 1 herein we also affirm the rejection of claims 9-13. Appellants have not indicated specific error in the Examiner's rejection or provided specific rebuttal argument for claims 9-13.

Claims 30 and 142

We select claim 30 as representative of this claim grouping. Claim 30 is directed to "A composition as set forth in claim 29, further comprising a composition that ameliorates a decline in post challenge performance."

Specific examples of ameliorating compositions are set forth on page 44 of the Specification. Examples of compositions which ameliorate a decline or decrease in post-challenge performance include, for example, cytokines, growth factors, chemokines, mitogens, and adjuvants. (Spec. 44.)

Appellants contend that the Examiner has provided no evidence in Conkle of a composition which ameliorates a decrease in post challenge performance. (App. Br. 22-23.) The Examiner argues that "limitations such as 'the composition ameliorates a decline or decrease in post-challenge performance' . . . are being viewed as inherent and a limitation of intended use" (Answer 3-4).

We agree with Appellants and do not find that the Examiner has provided evidence that Conkle teaches a composition for the control of coccidiosis further comprising a composition that ameliorates a decline in post challenge performance, or that such a property is inherent in Conkle's composition. The rejection of claims 30 and 142 as anticipation by Conkle is reversed.

Claim 113

Appellants argue that claim 113 depends from claim 1 and is directed to a kit with instructions for use. (App. Br. 23.) Appellants contend that the composition of the invention may be administered by a variety of routes and

may require dilution before administration, and indicate that the instructions provide this information. (App. Br. 24.)

> Applicants submit that the instructions in the kit of claim 113 do not constitute a mere intended use, but instead are functionally related to the composition, and therefore should be given patentable weight. As stated by the Federal Circuit in *In re Gulack*, "Under section 103, the board cannot dissect a claim, excise the printed matter from it, and declare the remaining portion of the mutilated claim to be unpatentable. The claim must be read as a whole." Furthermore, "[t]he fact that printed matter by itself is not patentable subject matter, because non-statutory, is no reason for ignoring it when the claim is directed to a combination." The compositions of the invention may be administered by a variety of routes, and may require dilution before administration. The instructions in claim 113 deal with these physical alternatives and, thus, allow the user of the kit to gain the additional benefit of a properly prepared and administered composition.

(App. Br. 24.)

The Examiner finds that Conkle anticipates claim 113 because the "instruction" limitation carries no patentable weight. (Ans. 4.)

We agree with the Examiner that the "package insert (instructions) does not lend patentable weight as a limitation of the claimed product, composition, or article of manufacture, absent a functional relationship between package insert and the product, composition of matter or article of manufacture." (Answer 4.) *See*,

> *In re Venezia* 530 F.2d 956 (CCPA 1976), where kits are drawn to the structural attributes of interrelated component parts and not to activities that may or may not occur. Further, *In re Miller* 418 F.2d 1392 (CCPA 1969) and *In re Gulack*, 703 F.2d 1381, 1386 (Fed. Cir. 1983), relate to a mathematical device and to a measuring cup respectively. In each of these cases, the printed

> matter is considered a patentable distinction because the function of the device depends upon the printed matter itself which is a part of the substrate; without the printed indicia or numbers, the substrates lose their function. Such is not the case with the instantly claimed articles.

(*Id.*)

We agree with the Examiner that

> In the instant case, the claims are drawn to a composition which comprises oocysts and instructions for administration of the said composition to an animal. The intended use which is recited on the package insert lacks a function relationship to the composition because the insert does not physically or chemically affect the chemical nature of the composition and furthermore, the composition can still be used by the skilled artisan for other purposes. Therefore, instructions for administering the composition is unpatentable over the prior art because the composition functions equally effectively with or without the package insert, and accordingly *no functional relationship exists between the instructions for use and the composition*.

(Ans. 5-6.)

In the present case, the only difference between the prior art product and the claimed product is printed matter that is not functionally related to the product, and the content of the printed matter will not distinguish the claimed product from the prior art. *In re Ngai*, 367 F.3d 1336, 1339 (Fed. Cir. 2004). The polypeptides of the claimed composition for control of coccidiosis remain fully functional absent the labeling or printed instructions for use. Thus, the instructions on the package insert bear no patentable weight. (Ans. 5.)

Appellants also argue that claim 113 is further rejected for the same reasons as claim 1. (App. Br. 23.) For the reasons given for claim 1 herein we also affirm the rejection of claim 113.

Claims 114-116 and 118-119

Claims 114-116 and 118-119 depend directly or indirectly from claim 113 and are thus patentable for the same reasons as set forth above for claim 113 as well as for the additional elements they require. Appellants have not indicated specific error in the Examiner's rejection or provided specific rebuttal argument for claims 114-116, and 118-119.

For the reasons give for claim 113, the rejection of claims 114-116, 118, and 119 is affirmed.

Claim 139

The Examiner rejects claim 139 on the basis that the phrase "a ratio defined by the minimum immunizing dose and amount determined by storage half-life determinations" is inherent and is a limitation of intended use. (Ans. 25.)

Appellants argue that claim 139 depends indirectly on claim 1 and is thus patentable for the same reasons as set forth above for claim 1. (App. Br. 25.)

Appellants also argue that the phrase

> "...a ratio defined by the minimum immunizing dose and amount determined by storage half-life determinations" is a quantification of a dosage amount contained in the composition, not a mere limitation of intended use. Such quantification cannot be found inherently in Conkle, et al. based on the reference's general disclosure that encysted protozoa oocysts

> including *Eimeria maxima, E. mitis, E. tenella, E. acervulina, E. brunetti, E. necatrix, E. praecox*, and mixtures thereof can be given in a single vaccine. There is no remote connection between this disclosure and the combination of ratio and amounts that is claimed.

(App. Br. 25.)

Appellants argue that not "only is quantification defined by the ratio and amounts specified in claim 139 entirely structural, but it also imparts a critically desirable feature to the claimed composition." (App. Br. 26.) Appellants contend that "[s]ince a certain number of sporulated oocysts cease to be functional as they age, providing a quantity of sporulated oocysts as defined by claim 139 helps to assure that quantity of viable oocysts will be sufficient for the vaccine to be effective when used." *Id.*

> Appellants argue that
>
> For this purpose, the minimum number of sporulated oocysts of each *Eimeria* species in the composition may be determined using the minimum immunizing dose and the storage half-life of the sporulated oocysts. As those skilled in the art will readily understand from applicants' specification, the half life defines the slope of the logarithmic decay curve. Back projection on this curve over a period corresponding to storage life defines the amount of oocysts that must be contained in the original dose package in order to assure that minimum immunizing dose remains on the day of administration. By further supplying the plural oocysts in ratios determined by their respective minimum immunizing doses, the claimed combination avoids supplying an excess of one species while supplying a sufficiency of all three, thus assuring efficacy without compromising bird performance.

Id.

Appellants argue that the Examiner has provided "no evidence whatsoever to support the contention that the claim limitation 'a ratio defined by the minimum immunizing dose and amount determined by storage half-life determinations' is inherent in Conkle." *Id.*

We are not persuaded. Conkle teaches a vaccine including multiple strains of protozoal oocysts. We agree with the Examiner that because Conkle discloses such a mixture is a vaccine which would by definition include at least an immunizing dose that it would include a ratio defined by a minimum immunizing dose. (*See, e.g.*, Ans. 35.) Further, because the vaccine of Conkle includes a similar number of oocysts as the vaccine disclosed in the Specification, page 45, then Conkle includes a minimum immunizing dose and an amount determined by storage half-life determinations. Appellants have not provided evidence that Conkle does not provide a minimum immunizing dose of oocysts or that the amount of oocysts disclosed in Conkle is not the same as the claimed amount determined by storage half-life determinations.

This rejection is affirmed.

2. *Obviousness over Conkle and Brown*

Claims 1, 4-30, 113-116, 118-119, 136-143, 146, 148-150, and 153-154 stand rejected under 35 U.S.C. §103(a) over Conkle in view of Brown.

We select claim 1 as representative of claims 2-22, 29, 113-116, 118-119, 136-141, 146, 148-150, and 153-154 since these claims are not separately argued.

Appellants argue that Brown is relied on by the Examiner solely for its disclosure of *P. acnes* and that Brown adds nothing to the teachings of

Conkle. (App. Br. 28.) "Thus, citation of the Brown, et al. reference would appear to have relevance only with respect to claims 23-28, 30, 142, and 143, which call for a component composition which ameliorates a decline in post- challenge performance, and specifically to claims 26-28 and 143 which expressly call for the presence of *P. acnes*." (App. Br. 28.)

Appellants argue that

> As explained above, the express exclusion of "bacterial contaminants which are present in said source" and the product-by-process limitations in claim 1 impose structural limitations on the claim that distinguish it from the cited references. In particular, the composition of claim 1 comprises a lower amount of non-viable bacterial contaminants than the composition of Conkle, et al. alone, or in combination with the *P. acnes* described in Brown, et al. Since there is no disclosure or suggestion in either Conkle, et al. or in Brown, et al. of oocyst containing compositions that are substantially free of bacterial contaminants which are present in a source but have been separated from the oocysts by tangential flow filtration of an aqueous process medium containing the oocysts and the bacterial contaminants using a filter membrane having a pore size such that sporulated oocysts cannot enter the pores, but the bacterial contaminants can pass through the pores, the cited references fail to teach or suggest all the limitations of claim 1.

(App. Br. 29.)

Appellants argue that

> Brown, et al. do not suggest removing any non-viable bacterial contaminants from the vaccine, much less reducing them to the level that is achieved by tangential flow filtration as defined in applicants' claims.
>
> In addition, the composition of claim 1 provides an advantage over other compositions (such as the composition of Conkle, et al. alone or in combination with the *P. acnes* of

> Brown, et al.) in that the lower amount of non-viable bacterial contaminants reduces the risk that animals administered the composition will experience a pyrogenic reaction. Applicants thus submit that the composition of claim 1 has an unexpected and unique property (in this instance lower amount of non-viable bacterial contaminants that results in freedom from an adverse side effect inherent in the compositions of the cited references) that further distinguishes it from the compositions disclosed in the cited references.

Id.

Appellants' arguments have been addressed with respect to the rejection of claim 1 over Conkle and have been found unconvincing. "Conkle et al teach that in a preferred embodiment of the invention the oxidant is a biocide, hydrogen peroxide or chlorine (page 8)." (FF 2.) Conkle teaches the use of a bleaching agent such as sodium hypocholorite (FF 2). Thus Conkle describes removal of bacterial contamination from the oocysts by bleaching or use of biocides. The Examiner has shown a sound basis for believing that the product of Appellants and the prior art are the same. The Appellants have the burden of showing that they are not. We do not find that Appellants have provided comparative evidence that Appellants' product is different from the product disclosed by Conkle. Appellants' arguments with respect to claims 23-28, 30, 142, and 143 are addressed separately below. The rejection of claim 1 over Conkle in view of Brown is affirmed. Claims 2-22, 29, 113-116, 118-119, 136-141, 146, 148-150, and 153-154 fall with claim 1.

Claims 23-28, 30, and 142-143

We select claim 30 as representative of this claim grouping.

According to Appellants

> Claims 23, 30, and 142 are indirectly dependent on claim 1, and are thus patentable for the same reasons as set forth above for claim 1. Furthermore, applicants again note that the Examiner has appeared to misinterpret claims 23, 30, and 142, stating that claim limitations such as "the composition ameliorates a decline in post-challenge performance" is being viewed as a limitation of intended use.
>
> As noted above, the phrase "which ameliorates a decrease [or decline] in post-challenge performance" does not specify a mere property of the composition as a whole, but instead defines an additional component of that composition by a functional characteristic which that component possesses. The phrase "which ameliorates a decrease [or decline] in post-challenge performance" thus does not refer to a mere intended use, but rather, to an ameliorating composition which is a component of the composition of claims 23, 30, and 142.

(App. Br. 32-33.)

Brown teaches a composition of *P. acnes* used in immunizing against coccidiosis (FF6). The Specification discloses that *P. acnes* ameliorates a decrease in post challenge performance in conjunction with a vaccine for the control of coccidiosis. (FF4.) Conkle teaches a vaccine for the control of coccidiosis. (FF1.) The Examiner concludes that

> It would be *prima facie* obvious at the time the invention was made to add the composition comprising *Propionibacterium acnes* as taught by Brown et al to the compositions comprising oocysts from the genus Eimeria of Conkle et al because Brown et al teach compositions comprising *Propionibacterium acnes* and normal saline used for stimulating non-specific cell mediated immune responses in poultry at an age as early as one [day] or even *in ovo* and to combat coccidiosis and other poultry diseases. It would be expected barring evidence to the contrary that a composition

> comprising sporulated oocysts, a diluent, a buffer and a bactericide would be effective in preventing coccidiosis in animals.

Id. at 9-10. (FF9.) We agree with the Examiner's rationale and further find that it would have been obvious to one of ordinary skill in the art to substitute the vaccine used in the method of Brown with the vaccine of Conkle. Appellants have not demonstrated error in the Examiner's rejection. This rejection of claims 30 is affirmed. Claims 23-28 and 142-143 fall with claim 30.

Claim 139

According to Appellants

> The Examiner has also stated with regard to claim 139 that the phrase "a ratio defined by the minimum immunizing dose and amount determined by storage half-life determinations" is a limitation of intended use.
>
> Claim 139 depends indirectly from claim 1 and is thus patentable for the same reasons as set forth above for claim 1. Furthermore, for the reasons set forth above, it is respectfully submitted that the phrase "…a ratio defined by the minimum immunizing dose and amount determined by storage half-life determinations" is more than a mere limitation of intended use, but rather is a further structural limitation that quantifies the amounts of *E. acervulina, E. maxima, and E. tenella* sporulated oocysts and ratios thereof that are present in the claimed composition.

(App. Br. 33.)

Additionally Appellants argue that "the cited references fail to teach or suggest any ratio of *E. acervulina, E. maxima, and E. tenella*, present in their composition, nor do either of the cited references recognize the

problem of aging of sporulated oocysts during shipping and storage, much less how to determine a suitable" ratio. (App. Br. 33-34.)

As discussed herein, we are not persuaded. Conkle teaches a vaccine including multiple strains of protozoal oocysts. (FF3.) We agree with the Examiner that because Conkle discloses such a mixture is a vaccine which would by definition include at least an immunizing dose that it would include a ratio defined by a minimum immunizing dose. (*See, e.g.*, Ans. 35.) Further, the vaccine of Conkle includes a similar number of oocysts as the vaccine according to the Specification, page 45, and thus includes a minimum immunizing dose and an amount determined by storage half-life determinations. Appellants have not provided evidence that Conkle does not provide a minimum immunizing dose of oocysts or that the amount of oocysts disclosed in Conkle is not the same as the claimed amount determined by storage half-life determinations.

The rejection of claim 139 is affirmed.

3. *Anticipation over Evans*

Claims 1, 4-22, 29-30, 113-116, 118-119, 136-142, 146, 148-150, and 153-154 stand rejected under 35 U.S.C. §102(a) as being anticipated by Evans.

We select claim 1 as representative of this rejection and address separately argued claims below.

Appellants argue that Evans

> fail to disclose or suggest a sporulated oocyst-containing composition that is substantially free of bacterial contaminants that are present in a source but that have been separated from the oocysts by tangential flow filtration of an aqueous process

> medium containing the oocysts and the bacterial contaminants using a filter membrane with a pore size small enough to prevent sporulated oocysts from entering the pores, but large enough to allow bacteria to pass through the pores.

(App. Br. 34.)

For example, Appellants argue that Evans does not even disclose the use of tangential flow filtration, much less the use of a filter pore size small enough no prevent sporulated oocysts from entering the pores, but large enough to allow bacteria to pass through the pores. (App. Br. 34-35.) Evans states

> that repeated washings, which involve collection of oocysts by centrifugation and resuspending in deionized or distilled water, may be used to remove the potassium dichromate from the oocyst suspension, and that repeated washings may be used to remove sodium hypochlorite from the oocysts. But Evans []do not suggest that such washings would remove non-viable contaminants from the compositions, and there is no basis in the record to infer that the process described by Evans, et al. might inherently remove non-viable bacterial contaminants. In this regard, applicants note that the centrifugation of an oocyst suspension followed by resuspending in water will not necessarily remove non-viable bacterial contaminants to the extent the tangential flow filtration described in claim 1 does; and, in any case, Evans, et al. fail to disclose centrifugation conditions that would be effective to retain bacterial contaminants in the centrate.
>
> Furthermore, Evans, et al. do not suggest or recognize the desirability of separating the oocysts from non-viable bacterial or other contaminants that may be present in the oocyst suspension. Evans, et al. fail to even recognize the problems associated with oocyst-containing compositions that comprise non-viable bacteria or bacterial debris, much less how such problems may be addressed.

(App. Br. 35.)

We are not convinced by Appellants' argument. "Evans et al teach that oocysts of the invention can be treated with sodium hypochlorite and then sporulated (page 5)." (FF 12.) Thus Evans removes bacterial contamination from its vaccine composition in the same manner as Conkle.

Evans et al teach that a typical dose of sporulated oocysts is 200,000 oocysts/bird (page 5). Evans teaches that oocysts of the invention can be treated with sodium hypochlorite and then sporulated (page 5). Evans et al teach that potassium dichromate is removed from the suspension by repeated washing of the oocysts (page 6), therefore the claim limitation , "...less than about 0.4% by weight of alkali metal dichromate" is taught by the prior art. (Ans. 10.)

Evans indicates that purification of merozoites to remove host cell debris can be done by various methods known in the art. (Evans, 7.) The Examiner has shown a sound basis for believing that the product of Appellants and the prior art are the same. The Appellants have the burden of showing that they are not.

Appellants have failed to provide comparative evidence that Appellants product has a degree of purification that is greater than the purification disclosed by Evans. Appellants' argument cannot take the place of evidence.

The anticipation rejection of claim 1 over Evans is affirmed.

Claims 4-8, 14-22, 29-30, 113-116, 118-119, 136-142, 146, 148-150, and 153-154

Appellants argue that "Claims 4-8, 14-22, 29-30, 113-116, 118-119, 136-142, 146, 148-150, and 153-154 depend either directly or indirectly from claim 1 and are thus patentable for the same reasons as set forth above for claim 1 as well as for the additional elements they require." (App. Br. 38.)

Appellants have not indicated specific error in the Examiner's rejection. For the reasons provided for claim 1 over Evans, the rejection of claims 4-8, 14-22, 29-30, 113-116, 118-119, 136-142, 146, 148-150, and 153-154 is affirmed.

Claim 9-13

Appellants argue that "Claim 9 is similar to claim 1, except the composition contains at least about 300 oocysts per milliliter and less than about 0.002% by weight of alkali metal dichromate. Claim 10 is similar to claim 1, except the composition contains less than about 5.0×10^{-3} µg of alkali metal dichromate per oocyst and has no limitation on the amount of oocysts per milliliter." (App. Br. 38.)

Appellants argue that claims 9 and 10, as well as claims 11-13 which depend either directly or indirectly from claim 10, are patentable for the same reasons as set forth above for claim 1.

For the reasons provided for claim 1 over Evans, the rejection of claims 9-13 is affirmed.

Claims 30, 113-116, 118-119, 139, and 142

We select claim 30 as representative of this claim grouping.

According to Appellants

> The final office action … reiterates previous comments that the phrase "the composition ameliorates a decline or decrease in post-challenge performance" (as applied to claims 30 and 142), that the phrase "a ratio is defined by the minimum immunizing dose and amount determined by storage [half]-life determinations" (as applied to claim 139), and that kits and package inserts (as applied to claims 113-116 and 118-119) are being viewed as limitations of intended use. In response to these comments, applicants refer to the arguments made above with respect to Conkle, et al., and submit that a similar line of reasoning applies in the context of the Evans, et al. reference.

(App. Br. 38.)

Unlike Conkle, Exans discloses that immune stimulants such as cytokines may be used in conjunction with its vaccine. (Evans 8, ll. 19-20.) According to Appellants' Specification, the composition which ameliorates a decline or decrease in post-challenge performance includes cytokines. (FF21.) In addition, we agree with the Examiner that because Evans discloses such a mixture is a vaccine which would by definition include at least an immunizing dose (FF22) in an overlapping dose that it would include a ratio defined by a minimum immunizing dose. (*See, e.g.*, Ans. 35.)

For the reasons herein, the rejection of claim 30 is affirmed. Claims 113-116, 118, 119, 139, and 142 fall together with claim 30.

4. *Obviousness over Evans and Brown*

Claims 1, 4-30, 113-116, 118-119, 136-143, 146, 148-150, and 153-154 stand rejected under 35 U.S.C. §103(a) over Evans in view of Brown.

We select claim 1 as representative of claims not separately argued below, i.e., claims 4-22, 24-29, 113-116, 118-119, 136-138, 140-141, 143, 146, 148-150, and 153-154.

> [A]pplicants again submit that the express exclusion of "bacterial contaminants which are present in said source" and the product-by-process limitations in claim 1 impose a structural limitation on the claim that distinguishes it from the cited references. In particular, the composition of claim 1 contains a much lower amount of bacterial contaminants (both viable and non-viable) than would be present were the pore size small enough to retain bacteria as well as oocysts. Since there is no disclosure or suggestion in either Evans, et al. or in Brown, et al. (nor any motivation to modify the cited references) of oocyst containing compositions that are substantially free of bacterial contaminants which are present in a source but have been separated from the oocysts by tangential flow filtration of an aqueous process medium containing the oocysts and the bacterial contaminants using a filter membrane having a pore size such that sporulated oocysts cannot enter the pores, but the bacterial contaminants can pass through the pores, the cited references fail to teach or suggest all the limitations of claim 1.

(App. Br. 40.)

Appellants have failed to provide comparative evidence that Appellants product has a degree of purification that is greater than the purification disclosed by Evans, or that its process results in a product with properties different from the product of Evans. Appellants' argument cannot take the place of evidence.

The obviousness rejection of claim 1 over Evans in view of Brown is affirmed. Claims 4-22, 24-29, 113-116, 118-119, 136-138, 140-141, 143, 146, 148-150, and 153-154 fall with claim 1.

Claims 23, 30, and 142

We select claim 30 as representative of this claim grouping.

According to Appellants

> Claims 23, 30, and 142 are indirectly dependent on claim 1, and are thus patentable for the same reasons as set forth above for claim 1. Furthermore, applicants again note that the Examiner has appeared to misinterpret claims 23, 30, and 142, stating that claim limitations such as "the composition ameliorates a decline in post-challenge performance" is being viewed as a limitation of intended use. For the reasons set forth above, applicants respectfully submit that the phrase "which ameliorates a decrease [or decline] in post-challenge performance" does not refer to a mere intended use, but rather, to an ameliorating composition which is a component of the composition of claims 23, 30, and 142.

(App. Br. 42.)

For the reasons provided for claim 30 over Evans, the rejection of claim 30 is affirmed. Claims 23 and 142 fall with claim 30.

Claim 139

According to Appellants

> The Examiner has … stated with regard to claim 139 that the phrase "a ratio defined by the minimum immunizing dose and amount determined by storage half-life determinations" is a limitation of intended use.
>
> As discussed above, claim 139 depends indirectly from claim 1 and is thus patentable for the same reasons as set forth above for claim 1. Furthermore, for the reasons set forth above, it is respectfully submitted that the phrase "...a ratio defined by the minimum immunizing dose and amount determined by storage half-life determinations" is more than a mere limitation

> of intended use, but rather is a structural limitation that quantifies the amounts of *E. acervulina, E. maxima, and E. tenella* sporulated oocysts and ratios thereof that are present in the claimed composition.
>
> Additionally, the cited references fail to teach or suggest any ratio of *E. acervulina, E. maxima, and E. tenella,* present in their compositions, nor do either of the cited references recognize the problem of aging of sporulated oocysts during shipping and storage, much less how to determine a suitable amount of oocysts by storage half-life determinations. Claim 139 is thus patentable over the cited references for this additional reason.

(App. Br. 39.)

This argument is not persuasive. Evans teaches a vaccine such as a vaccine including multiple strains of protozoal oocysts. (FF22.) We agree with the Examiner that because Evans discloses such a mixture is a vaccine which would by definition include at least an immunizing dose and an overlapping dosage range (FF22) that it would include a ratio defined by a minimum immunizing dose. (*See, e.g.*, Ans. 35.) Further, if such composition includes a similar number of oocysts according to the Specification, page 45, it includes a minimum immunizing dose and an amount determined by storage half-life determinations. Appellants have not provided evidence that Evans does not provide a minimum immunizing dose of oocysts or that the amount of oocysts disclosed in Evans is not the same as the claimed amount determined by storage half-life determinations.

The rejection of claim 139 is affirmed.

SUMMARY

All rejections for anticipation and obviousness are affirmed, except the rejections of claims 30 and 142 for anticipation by Conkle are reversed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

cdc

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